Validity of a diagnostic method is not a quantity that remains constant in different situations. It is affected by the ratio of true positives to false positives: it is bound to be lower in a population where the condition in question is rare than in a population where the prevalence is high, and similarly it will be lower in a population that has a high prevalence of the conditions that give rise to false positive classifications, The validity of the angina questionnaire, for example, may be lower in a population where chronic bronchitis is common than in one where it is rare. The complete standardization of validity is unattainable.

Standardization of diagnostic methods has often originated in epidemiological research. Problems can arise when a method designed for the description of groups is used for case-finding and diagnosis. The seriousness of a particular kind of error in the individual case may be very different, and the balance between sensitivity and specificity that is optimal for the epidemiologist may be inappropriate for the diagnostician. The idea of a single, standard method that is suitable for all situations is sometimes mistaken.

Standardization, then, is not an unmixed blessing. It facilitates communication between investigators, as Professor Wing has shown; it may promote the development of more efficient means of discrimination, as indicated by Dr Edwards; and finally, as Dr Hull pointed out, it simplifies the application of diagnostic techniques. But at the same time it tends to inhibit experiment in new methods of measuring disease and the search for new kinds of diagnostic information; and it offers us one method where sometimes we might be better served by having more than one, each appropriate to a particular need. How then do we decide how far standardization should proceed? By exposing some of the underlying complexities, our speakers have put us in a better position to tackle these rather difficult problems.

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Communicable Disease Surveillance

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Evolution of the Concept of Surveillance in the United States

Until twenty years ago, the term surveillance had a restricted meaning in public health practice. It was applied to individuals, primarily to contacts of serious communicable diseases such as pneumonic plague, who were closely watched for the development of first signs of illness. Surveillance required judicious alertness to detect a possible problem and enlightened responsibility to see that effective action was taken, if impending trouble developed. In 1950 the Center for Disease Control (CDC, formerly the Communicable Disease Center) of the US Public Health Service in Atlanta, Georgia, broadened the use of the term surveillance by applying it to a disease rather than to an individual (Langmuir 1963). The first disease was malaria but thereafter each communicable disease of national importance was added to the systematic programme. Now the term is routinely applied also to a wide variety of conditions, such as leukæmia, congenital defects, abortions and drug reactions, and to many environmental monitoring functions such as radioactive fallout and air pollution indices. During the past decade, under the leadership of Dr Karel Raska, surveillance has taken on an international significance, first in Czechoslovakia and then on a global scale through the World Health Organization (Raska 1966). In 1968, the Technical Discussions of the World Health Assembly were devoted to a full examination of surveillance as an established and essential function of public health practice. In this paper I will review the major steps in the evolution of this concept in the United States, illustrate some of its uses and propose certain limitations in its scope.

Immediately following World War II, the United States embarked on a major programme to eradicate malaria. The disease had long been established in fourteen traditionally malarious states and serious epidemics had appeared in the economic depression of the mid-1930s. The advent

of DDT gave promise that total control would be achieved; to some this was courageous leadership but to many traditionalists it was foolhardy and not ecologically sound public health. Little did either group appreciate the real situation.

The CDC was established in Atlanta to conduct this programme. DDT was sprayed on the walls of houses in the rural South. The practical operational aspects of the programme took precedence over the development of epidemiological evaluation; the engineers argued that tens of thousands of cases of malaria were being reported and many hundreds of positive laboratory specimens were being seen in public health laboratories. Why waste money on counting cases when you know there are plenty? In 1950, however, a planned surveillance was formally undertaken on a national scale: case reports were systematically investigated, laboratory-confirmed cases were checked for source of infection. This reasonably basic traditional epidemiological procedure revealed the remarkable facts that: (1) Most reports were erroneous and emanated from older practising physicians in rural areas. (2) The few laboratory-confirmed cases were either imported from overseas or relapses of old infections. (3) No epidemics or localized clusters of malaria could be identified. Looking back over the preceding 5 years, it soon became apparent that malaria had spontaneously disappeared during the early 1940s and that the scientific basis of the national malaria eradication programme had not been well-founded. The value of a systematic surveillance programme became abundantly clear.

From 1950 to 1960 surveillance played perhaps its most spectacular role in the conquest of poliomyelitis. Following World War II, epidemics appeared with increasing frequency and severity and began to involve progressively older children and more and more adults. A major activity of the CDC was epidemic investigation and orderly collection and analysis of morbidity and mortality data. This provided a basis of practical knowledge and a cadre of trained epidemiologists which were to be of great value later. The term surveillance was first applied to these poliomyelitis activities in April 1955 when the emergency of the Cutter Incident broke upon us. Cases of inoculation poliomyelitis both among inoculees and contacts of inoculees brought the enthusiastic polio vaccination programme to a screeching halt. The Surgeon General formally requested all states to collaborate in a national surveillance programme to be co-ordinated at the CDC. A detailed investigation was made of each case of poliomyelitis or suspect poliomyelitis and promptly reported; the data were collated by CDC and reported in full on a daily basis to a selected mailing list of health officials, vaccine manufacturers and members of advisory councils; weekly analytical summaries were prepared and distributed. These reports formed the basis for consistent news releases to the public and, most important, kept all those in responsible positions fully informed of new developments as they arose so that decisions in committee were made from a common basis of fact.

It soon became apparent that the problem was related to two production batches of vaccine from a single manufacturer and not an intrinsic flaw in the process of making formalin-inactivated vaccine. Production methods were tightened, safety testing strengthened, and the national programme reinstituted.

So also did the surveillance programme proceed and guide, step by step, the successful conquest of poliomyelitis. Many problems were encountered and solved including: the splitting out of the ECHO and Coxsackie infections which caused illnesses resembling polio; problems of low potency of vaccine necessitating change in inoculation schedules; the presence of SV-40 virus as a contaminant of the vaccine; and the occurrence of cases related to the oral vaccines, particularly Type 3 cases, among adults. The end result is familiar to all. Once a major absorption of the staff at CDC and of epidemiologists and health officers throughout the country, poliomyelitis now is a rare disease requiring a continual surveillance and an ongoing immunization programme but only a minimum of expenditure of specialized professional time and effort.

In 1957 when the pandemic of Asian influenza appeared, the CDC was directed to undertake an influenza surveillance programme like the poliomyelitis programme. Similar procedures were followed, i.e.: (1) Collecting all pertinent information such as current reports on epidemics, laboratory isolations, clinical characteristics of the disease, frequency of complications, information on new vaccines. (2) Collating and evaluating this mass of information on a day-to-day basis. (3) Disseminating the information in appropriate and assimilable form both to professional groups and to the general public.

Since 1957, influenza epidemics have continued to be a major, serious and seemingly intractable health problem, as frustrating to an action-and-control-orientated epidemiologist as poliomyelitis has been gratifying.

During the past decade these principles of surveillance have been applied in the United States to virtually all nationally recognized disease problems including: viral hepatitis, an increasing problem; salmonellosis and shigellosis, continuing endemic problems; nosocomial infections, a major and long ignored complex of

diseases; and measles and rubella, where we seem to be re-living the same types of problems we experienced with polio vaccines.

Instead of recounting further details on these specific disease problems, I believe I can more constructively comment on four broad practical issues concerning the concept of surveillance as it is developing.

Cost

Many have asked how it is possible to set up such seemingly complex machinery on a national scale and how it can be financed. In fact, surveillance is basically not an inordinately expensive operation. The essential information upon which surveillance depends exists at the local level, in the physicians' records, at the hospital, the laboratory and the health department. Surveillance is an orderly method of collecting new information promptly and systematically, screening, sorting and evaluating it, and of disseminating it regularly in appropriate and assimilable forms to those who need to know, including the general public. The obvious savings that come from the prompt recognition of an epidemic problem greatly exceed the cost of the surveillance system. The one essential requirement for a surveillance system is a reasonably sophisticated epidemiologist who is located in a central position in the health structure, who has access to information on the occurrence of communicable disease, who has power to inquire into and verify his facts and who has the ear and confidence of his chief medical officer of health.

Types of Reports

A variety of reporting mechanisms are needed in a well-developed surveillance system. The key is an open communication system, free of bureaucratic restraints, from the central surveillance office to the state and local health authorities and to the laboratories providing the diagnostic services. In the USA the following reporting mechanisms are used:

Telephone: We encourage the widest possible use of the telephone to follow up any lead as soon as it arises, or to report significant information without delay. The very process of using the telephone builds a personal relationship of confidence and encourages later reciprocation.

Morbidity-mortality weekly report (MMWR): Each Wednesday evening the MMWR goes to press and the printed report is mailed early the next day to approximately 20,000 readers. Intrinsically this report is an archive containing tabulations of the official notifications received from the State health departments for the preceding week. Prior to 1960 these data were published with little or no commentary, but during the past decade narrative accounts of current epidemics, surveillance summaries and often news relevant to communicable disease control have been added to the archival tables. This MMWR has become the central feature of the national surveillance programme. We like to think of this report as following in the great tradition established by William Farr in his Weekly Return of the General Register Office.

Special memoranda: Sometimes events arise of sufficient national interest to require more prompt notification of state and local health authorities than is possible in the MMWR. It is sometimes possible to disseminate this news by telephone but often a more definitive document is desirable and needs to be in the hands of several hundred persons. An emergency or special memorandum serves this purpose. Such a document is particularly useful when conflicting and often hysterical items have appeared in the popular press. An authoritative and definitive account serves to build confidence, allay hysteria and reduce the number of incessant inquiries to the surveillance office.

Detailed surveillance reports: Since the MMWR has serious restrictions of space, we issue a wide variety of detailed surveillance reports that deal in depth with the large volume of data that is received on many diseases. These reports are highly specialized, deal with a single disease or a group of closely related diseases and are circulated each to its own special mailing list of interested people. Essentially these surveillance reports keep faith with our sources of information in returning to them in detail the information they have submitted. These reports also serve as a stimulus to the continued submission of new information.

Sensitivity of the Method

The methods of surveillance are intrinsically crude and inaccurate. Reporting of cases is usually incomplete, verification of diagnosis is often lacking or delayed, adequacy of follow up of significant cases varies, and death registration, at least in the USA, is cumbersome. Yet with all these limitations the methods of surveillance, at certain times, can be extraordinarily sensitive and lead to prompt definitive action. Three illustrations follow:

(1) In 1955, two weeks after the announcement of the success of the Francis Field Trial of Salk poliomyelitis vaccine, 6 cases of paralytic disease were reported among recent recipients of the vaccine. These reports came in, one on the evening of April 25, and 5 on April 26. At 11 a.m. on April 27 the definitive control

action of recalling the vaccine of one manufacturer was taken. At that time perhaps five million doses of vaccine had been administered including 300,000 doses of the involved manufacturer. This incident occurred at a time of year when the normal incidence of poliomyelitis was minimal. Had the incident occurred during mid-summer it would have been more difficult to discern.

(2) In the summer of 1962 this very problem was encountered when cases of poliomyelitis were reported largely among adult males who had received monovalent Type 3 oral polio vaccine. With only 12 cases reported, several of which were most bizarre, a special board chaired by the Surgeon General was convened to inquire into the problem. Although it took two years to resolve this one, the surveillance programme brought the problem to recognition on the basis of 12 cases among tens of millions of vaccinees.

(3) In 1964, routine reports were received of two cases of *Salmonella new brunswick* infection in infants who had consumed a popular brand of non-fat dried milk. Checking back on the surveillance records of this rare serotype revealed a slight increase in occurrence over the previous several months. Field investigation of those reports confirmed an association with non-fat dried milk. The full investigation revealed a total of 28 cases over a 6-month period. Extensive culturing of this product by the US Food and Drug Administration ensued. One large production plant was discovered to be heavily contaminated with *S. new brunswick*, and widespread contamination of other plants was also uncovered. As a result of this small and essentially routine surveillance operation all manufacturers of this important and popular food, produced in quantities of more than 100 million pounds a year, reviewed their production and quality control processes. Several large producers ceased production for a complete overhaul and reconstruction of their plants.

Limitations on the Term

In the evolution of the concept of surveillance over the past 20 years some enthusiasts have tended to expand its scope too far. In the WHO Malaria Eradication terminology surveillance embraces active measures of control, namely chemotherapy and insecticiding during the consolidation and maintenance phases of eradication. Some epidemiologists tend to define surveillance as synonymous with epidemiology in its broadest aspects including epidemiological investigation and research. This trend is, in my opinion, both etymologically unsound and administratively unwise. I favour the definition of surveillance as the general practice of epidemiology or epidemiological intelligence. The surveillance officer should be the alert eyes and ears of the health officer and he should advise regarding control measures needed, but the decision and the performance of the actual control operations must remain with the properly constituted health authority. Similarly the flow of surveillance data may well provide interesting leads for research investigations, but the actual performance of the research study should be recognized as a function separate from surveillance.

In conclusion, let us recognize that although surveillance as a term applied to disease problems as distinct from individual persons is of only recent vintage, the function is as old as epidemiology itself. Let us use the term wisely and recognize its proper limitations. Let us recognize that in our conduct of surveillance we should emulate the standard set by William Farr a century ago whose courage, comprehensiveness, fearlessness and epidemiological insight have not been equalled since.

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Epidemiological Surveillance with Particular Reference to the Use of Immunological Surveys

The national and global surveillance of communicable diseases was discussed at the XXI World Health Assembly in 1968 (unpublished document, A21/Technical Discussions/5) and generally recommended to the member states as a prerequisite for the effective control and prevention of communicable diseases (Langmuir 1963, Raska 1964, 1966). Morbidity reporting and mortality registration are generally considered as being of basic importance in surveillance activities. However, in view of the existing weaknesses of health services in most developing countries and the traditional apathy with regard to vital statistics of the medical sciences and public health services in many highly developed countries, the implementation of a surveillance programme for communicable diseases cannot wait until there is an improvement in morbidity and mortality reporting. Too much additional effort and time would be required. Fortunately, the surveillance of most infections does not depend solely on the availability of reliable morbidity data. Laboratory findings when standardized are objective, comparable and reproducible. Furthermore, immunological surveys could be made immediately in most developing countries with bilateral or international help. It is therefore evident that the

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